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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/938,703 | 08/24/2001 | Michel Samson | 9409/2023D | 1978 |
| 7590 03/25/2004 | | | | |
| KATHLEEN M. WILLIAMS PALMER & DODGE, LLP 111 HUNTINGTON AVENUE BOSTON, MA 02199 | | | | |
| EXAMINER SEHARASEYON, JEGATHEESAN | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1647 | | | | |

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|--------------------------------------|--|
| Office Action Summary | Application No. 09/938,703 | Applicant(s) SAMSON ET AL. | |
| | Examiner Jegatheesan Seharaseyon | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003 and 19 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57 and 59 is/are allowed.
- 6) ☒ Claim(s) 56, 58 and 60-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the amendment and remarks filed on 10/24/03 and 12/19/03. Claims 56-65 are pending. Applicants' remark about claim numbering is noted. Claims 60 and 65 have been amended.
2. Applicants correction of the priority information is acknowledged.
3. It is noted that the Applicants have provided corrected figure legends in response to the previous Office Action. The specification is also appropriately corrected.
4. Applicants amendment has obviated the objection to claim 60.
5. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, withdrawn

6. Rejection of claims 56-59 and 61-65 under 35 U.S.C. 112, first paragraph, as containing new matter and as failing to comply with the written description is withdrawn in view of Applicant's persuasive remarks.
7. New grounds of rejection.

Claim Rejections - 35 USC § 112

8. Claims 61-65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*
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The specification discloses antibodies including monoclonal antibodies, which are directed to an epitope of the peptide (see page: 8, last few lines). This meets the written description provision of 35 U.S.C. 112, first paragraph. However, the specification as originally filed does not disclose any antibody which binds to a polypeptide consisting at least four contiguous amino acid residues of the sequence of residues 185 to 215 of SEQ ID NO: 6. In addition, the specification also does not disclose an antibody, which binds to a polypeptide encoded by at least 12 contiguous nucleic acid residues of a sequence comprising residues 792 to 884 of SEQ ID NO: 3, wherein said polypeptide has the same reading frame as the sequence of SEQ ID NO: 6. The claims as written, however, encompass antibodies that bind amino acid sequences which were not originally contemplated and fail to meet the written description provision of 35 U.S.C. 112, first paragraph because the written description is not commensurate in scope with the recitation of claim 61-65. Thus, these antibodies were not described in the original disclosure and constitute new matter.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 56, 58, 60, 61, 63 and 65 rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (U. S. Patent No: 6, 025, 154).

The instant invention is directed to anti- Δ CCR5 antibody comprising variable regions.

Li et al. describe a human chemokine receptor polypeptide of SEQ ID NO: 2. It also describes antibodies against the receptor (column 2, lines 65-68 and column 16, lines 45-65). The receptor polypeptide of SEQ ID NO: 2 is 97.8% identical to SEQ ID NO: 6 of the instant invention amino acids 1-184 (see Appendix A). Thus antibodies that comprise amino acid residues 185 to 215 of SEQ ID NO: 6 could also bind to polypeptide of the instant invention (SEQ ID NO: 2). Therefore, claims 56, 58, 60, 61, 63 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al. (U. S. Patent No: 6, 025, 154).

10. Claims 57 and 59 are allowable. However, the disclosure is objected to because of the following informalities: The specification lacks antecedent basis for claims 57 and 59 and needs to be amended to refer to the claimed subject

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matter (see page 8, last paragraph). However, Applicant is reminded not to add NEW MATTER. Appropriate correction is required.

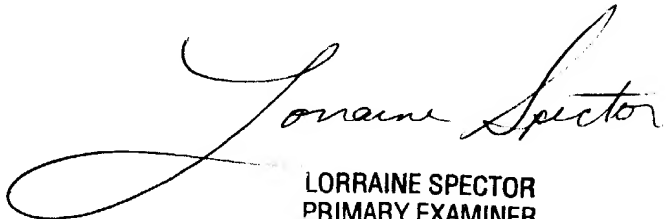
Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS


LORRAINE SPECTOR
PRIMARY EXAMINER